

July 15, 2004

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

RE: FDA Docket 2004P-0037

To Whom This May Concern:

The Academy of Dispensing Audiologists (ADA) requests that the following Citizen Petition be denied:

FDA Docket #2004P-0037 "513(f) Reclassification Petition- TV-TIP Sound Amplifier" proposed by Mead Killion, President, Etymotic Research, Inc.

This petition requests that the TV-TIP Sound Amplifier device be reclassified from class III, as classified by operation of section 513(f) (1) of the Federal Food, Drug and Cosmetic Act (the Act) under the criteria in Sec. 860.3 (c), to class I and exempted from premarket review under section 510(k) of the Act.

ADA is an organization of approximately 1200 audiologists whose current qualification for membership is limited to audiologists who have earned the Doctor of Audiology (Au.D.) degree. ADA Fellows provide diagnostic hearing examinations, hearing rehabilitation services, counseling services for hearing impaired patients and their families, hearing aid evaluations, hearing aid fittings and follow-up services as a part of their professional practices. Dispensing audiology has evolved to its current professional level because of the value the hearing impaired consumer places on the professional component in this important rehabilitation process.

ADA contends that the current Citizen Petition that Mead Killion, Ph.D. has proposed is along virtually identical lines to that of his Citizen Petition FDA docket #2003-P-0362 which was denied by your office earlier this

One Windsor Cove, Suite 305
Columbia, SC 29223
phone: (803) 252-5646
toll-free: 1-800-445-8629
fax: (803) 765-0860
email: info@audiologist.org
website: www.audiologist.org

RESIDENT
Cynthia Ellison, Au.D.
Bella Vista Hearing Center
Bella Vista, Arkansas
phone: (479) 876-0110
fax: (479) 876-0111
email: cynthia.ellison@worldnet.att.net

RESIDENT ELECT
Craig Johnson, Au.D.
Audiology Associates
Baltimore, Maryland
phone: (410) 944-3100
fax: (410) 298-6333
email: cjohn1@ix.netcom.com

PAST PRESIDENT
Robert Manning, Au.D.
Audiology Associates
Lexington, Kentucky
phone: (859) 277-0491
fax: (859) 276-2957
email: rmanning51@aol.com

TREASURER
David Berkey, Au.D.
The Hearing Center
Asheville, North Carolina
phone: (828) 277-1000
fax: (828) 277-1026
email: daveberkey@charter.net

SECRETARY
Lee Micken, Au.D.
Micken Hearing Services
Bozeman, Montana
phone: (406) 586-0914
fax: (406) 586-6667
email: micken@imt.net

GOVERNING BOARD DIRECTORS
Linda A. Burba, Au.D.
Audiologic Services, Ltd.
Glen Ellyn, Illinois
phone: (630) 858-3277
fax: (630) 858-6932
email: lindaburba@aol.com
Lawrence Michael Eng, Au.D.
Golden Gate Hearing Services
San Francisco, California
phone: (415) 931-8180
fax: (415) 931-1323
email: LarryAud@gghs.com
Larry Engelmann, Au.D.
Audiology Clinic
Oklahoma City, Oklahoma
phone: (405) 946-0364
fax: (405) 946-3036
email: mynnerear@cox.net

ADMINISTRATIVE AUDIOLOGIST
Susan Williamson Flory, Au.D.
Flat Rock, North Carolina
phone: (828) 692-7633
fax: (401) 735-5698
email: ADAFBEditor@aol.com

EDITORIAL EDITOR
Kevin Ruggle
Audiology Clinic, Inc.
Topeka, Kansas
phone: (785) 354-1552
fax: (785) 232-0153
email: druggle@kansas.net

ADMINISTRATION
Carol H. Webster
Executive Director
phone: (803) 252-5646
fax: (803) 765-0860
email: carol@jee.com
Nancy H. Cooper
Editor/Advertising/Website
phone: (803) 771-8983
fax: (803) 254-9725
email: ncooper@usit.net

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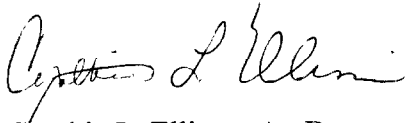
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year. That petition, as you may recall, was a "Petition to Create a New OTC Hearing Aid Classification that Grants OTC Sales, Distribution and Use Status to One-Size-Fits-Most Hearing Aid Devices".

Therefore, rather than preparing an entirely new document to refute Dr. Killion's request, we are resubmitting our response from January 2004. Our concerns with this present petition mirror those previously stated, i.e., safety and efficacy of the hearing impaired consumer.

We respectfully request that this new petition be denied as it may expose the consumer to significant health and safety risks. It is our continued belief that hearing impaired individuals are best served when the professional component is preserved.

Respectfully submitted on behalf of the Academy of Dispensing Audiologists,



Cynthia L. Ellison, Au.D.
President

Attachment: January 26, 2004 ADA reply to FDA Docket #2003-P-0362